

K070198
510(k) Summary

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Company Ethicon Endo-Surgery, LLC
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JUN 13 2007

Date Prepared January 19, 2007

Device Name Trade Name: Endopath® Dextrus™ Seal Cap Assembly with Accessories
and Endopath® Dextrus™ Fixed-Length Access Retractors

Common or Usual Names: Extended Laparoscopy Device; Access Retractors

Classification Names:

Laparoscope, General & Plastic Surgery [21 CFR 876.1500 (GCJ)]

Drape, Surgical, General & Plastic Surgery [21 CFR 878.4370 (KKX)]

Predicate Devices LAP DISC Hand Access Device (Hakko Medical Division of Hakko Shoji, Co. Ltd.), cleared under K030824 on June 4, 2003, K020307 on April 26, 2002, and K010870 on June 18, 2001

Alexis™ Wound Retractors (Applied Medical Resources Corp.), cleared under K020435 on April 15, 2002

Device Description The device is a sterile, single patient use abdominal access system comprised of two separately packaged components:

- Seal Cap Assembly with Accessories
- Fixed-Length Access Retractor

The ENDOPATH DEXTRUS Seal Cap Assembly consists of stationary and rotating rings interconnected by means of an elastomeric material that functions as an iris valve seal with an adjustable aperture. The seal cap assembly is designed to connect with the fixed-length access retractor. The assembled device can maintain peritoneal gas pressure while allowing for insertion of the surgeon's hand or surgical instruments into the abdominal cavity.

The Fixed-Length Access Retractor is available in three sizes to accommodate a wide range of abdominal wall thicknesses. The retractor consists of a top rigid ring and a bottom flexible ring interconnected by means of an elastomeric material. The top rigid ring provides for

circumferential wound retraction and is also the connection ring to the seal cap assembly. The bottom flexible ring is inserted into the abdomen for device fixation.

Accessories provided with the ENDOPATH DEXTRUS Seal Cap Assembly include a marking pen, ruler, and forearm wrap. The ruler and marking pen help measure and represent incision length, depending on surgeon glove size. The forearm wrap can be wrapped over the surgeon's glove and gown from the wrist to the upper forearm to facilitate the transition of the surgeon's gown through the iris valve during an extended reach within the abdominal cavity.

Indications for Use The ENDOPATH DEXTRUS Seal Cap Assembly with Accessories and Fixed-Length Access Retractors are indicated for use in procedures where entry of the surgeon's hand may facilitate the procedure, and for extraction of large specimens. The device has application in colorectal, urological, gynecologic, and general surgical procedures. This indication for use includes the specific procedures which fall under these broad categories.

The ENDOPATH DEXTRUS Seal Cap Assembly with Accessories, when used in conjunction with the ENDOPATH DEXTRUS Fixed-Length Access Retractor, is intended to provide extracorporeal extension of pneumoperitoneum and abdominal access for the surgeon during minimally invasive surgery.

The Fixed-Length Access Retractor, when used independently, is also intended to provide wound retraction and protection against wound contamination during minimally invasive and open surgery.

Technological Characteristics The ENDOPATH DEXTRUS Seal Cap Assembly and Fixed-Length Access Retractors are similar in design to the predicate device, the LAP DISC Hand Access Device. While the predicate device is a single piece design, the new device enables detachment of the seal cap assembly from the retractor. The sterilization method and materials differ from the predicate device. The new device includes the following accessories: marking pen, ruler, and forearm wrap.

Performance Data. Bench testing and preclinical laboratory evaluations were performed to demonstrate that the new device will perform as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ethicon Endo-Surgery, Inc.
% Ms. Wendy L. Turner, RAC
Director, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242-2839

JUN 13 2007

Re: K070198

Trade/Device Name: Endopath® Dextrus™ Seal Cap Assembly with Accessories and
Fixed-Length Access Retractors

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: GCJ

Dated: May 31, 2007

Received: June 1, 2007

Dear Ms. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

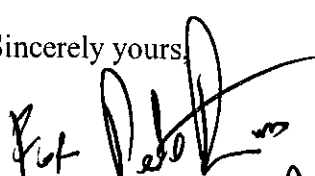
Page 2 – Ms. Wendy L. Turner, RAC

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070198

Device Name: Endopath® Dextrus™ Seal Cap Assembly with Accessories and Fixed-Length Access Retractors

Indications for Use:

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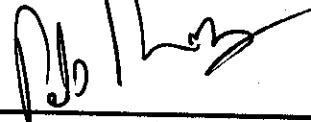
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices Page 1 of 1

(Posted November 13, 2003)

510(k) Number 12070198